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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
JONES, DWAYNE C

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/678,591	QUAY, STEVEN C.	
	Examiner	Art Unit	
	Dwayne C Jones	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-13,16-26,28-34,36-39 and 41-50* is/are pending in the application.

4a) Of the above claim(s) *2,14,15,27,35 and 40* is/are withdrawn from consideration.

5)☒ Claim(s) *1 and 3-12* is/are allowed.

6)☒ Claim(s) *13, 16-26, 28-34, 36-38, and 43* is/are rejected.

7)☒ Claim(s) *39,41,42 and 44-50* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of Claims

1. Claims 1, 3-13, 16-26, 28-34, 36-39, and 41-50 are pending.

2. Claims 13, 16-26, 28-34, 36-38, and 43 are rejected.

3. Claims 39, 41, 42, and 44-50 are objected.

4. Claims 1, 3-12 are allowed.

5. Claims 2, 14,15, 27, 35, and 40 are cancelled as per the amendment of November 2, 2003.

Response to Arguments

6. Applicant's arguments filed November 20, 2003 have been fully considered but they are not persuasive with respect to arguments regarding the composition claims. Applicant's attorney argues the following points. First, applicant argues that in the rejection of claims 26, 28-31, 33, 34, 36 and 37 under 35 U.S.C. 103(a) as being unpatentable over Harris et al. of U.S. Patent No. 5,482,931 is unfounded. Next, applicant alleges that the rejection under 35 U.S.C. 103(a) as being unpatentable over Harris et al. in view of Boer et al. and further in view of Leckman et al. is also not relevant to the instant claims.

7. Responding to applicant argument that the prior art reference of Harris et al. fails to teach or suggest the efficacy of carbetocin or another oxytocin analog for prophylaxis or treatment of breast cancer or a psychiatric disorder in a mammalian patient, the same above response is applicable to address this argument. For this reason, Harris et

al. is relevant art to reject claims because instant claims 26, 28-31, 33, 34, 36 and 37 are composition with the incorporation of an intended use of a compound. This argument is not found persuasive because the instantly rejected claims are composition claims with an intended use recitation.

8. Applicant next argues that the rejection under 35 U.S.C. 103(a) as being unpatentable over Harris et al. in view of Boer et al. and further in view of Leckman et al. Accordingly, this rejection was modified to reject claims 26, 28-31, 33, 34, 36, 37, and 38 under 35 U.S.C. 103(a) as being unpatentable over Harris et al. of U.S. Patent No. 5,482,931 in view of Leckman et al. It is once again pointed out that instant claims 26, 28-31, 33, 34, 36, 37, and 38 are composition claims, which happened to contain a functional recitation of an intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). For these reasons, the selection of a known material based on its suitability for its intended use, for example psychiatric disorder or breast cancer, supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 US 327, 65 USPQ 297 (1945).

Information Disclosure Statement

9. It is requested that a supplemental list be provided for the information disclosure statement filed on April 1, 2002 so that all of these references may be properly indicated as being considered. In particular if a particular reference was lined out that would indicate that the reference was not considered because it was not available. Please provide copies of the lined out references.

Claim Objections

10. Claim 45 is objected to as being dependent upon a rejected base claims 39, 41, and 43.

11. Claim 50 is objected to because of the following informalities: this claim does not end with a period. Appropriate correction is required.

Claim Rejections - 35 USC § 112

12. The rejection of claims 1-12 and 26-33 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of breast cancer, does not reasonably provide enablement for the prevention or prophylaxis of breast cancer is withdrawn in response to the amendment of November 20, 2003.

13. Claims 13, 16-25 and 34, 36-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of breast cancer with carbetocin, does not reasonably provide enablement for the treatment of other psychiatric disorders, including obsessive-compulsive disorder (OCD).

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The instant invention is directed to the treatment of OCD with the administration of carbetocin.

(2) The relative skill of those in the art

The relative skill of those in the art of pharmaceuticals is high.

(3) The predictability or unpredictability of the art

The unpredictability of the pharmaceutical art is very high. In fact, the courts have made a distinction between mechanical elements function the same in different circumstances, yielding predictable results, chemical and biological compounds often react unpredictably under different circumstances. Nationwide Chem. Corp. v. Wright,

458 F. Supp. 828, 839, 192 USPQ 95, 105(M.D. Fla. 1976); Aff'd 584 F.2d 714, 200 USPQ 257 (5th Cir. 1978); In re Fischer, 427 F.2d 833, 839, 166 USPQ 10, 24 (CCPA 1970). Thus, the physiological activity of a chemical or biological compound is considered to be an unpredictable art. For example, in Ex Parte Sudilovsky, the Court held that Appellant's invention directed to a method for preventing or treating a disease known as tardive dyskinesia using an angiotensin converting enzyme inhibitor involved unpredictable art because it concerned the pharmaceutical activity of the compound. 21 USPQ2d 1702, 1704-5 (BDAI 1991); In re Fisher, 427 F.2d 1557, 1562, 29 USPQ, 22 (holding that the physiological activity of compositions of adrenocorticotropic hormones was unpredictable art0; In re Wright, 999 F.2d 1557, 1562, 29 USPQ d, 1570, 1513-14 (Fed. Cir. 1993) (holding that the physiological activity of RNA viruses was unpredictable art); Ex Parte Hitzeman, 9 USPQ2d 1821, 1823 (BDAI 1987); Ex Parte Singh, 17 USPQ2d 1714, 1715, 1716 (BPAI 1990). Likewise, the physiological or pharmaceutical activity of carbetocin prior to filing of the instant invention was an unpredictable art.

(4) The breadth of the claims

The instant claims are very broad. For instance, claims 13 and 34 are directed to treating obsessive-compulsive disorder with the administration of carbetocin. The breadth of claims was a factor in Amgen v. Chugai Pharm. Co., 927 F.2d 1200, 18 USPQ2d (Fed. Cir.),cert. Denied, 502 U.S. 856 (1991). In the Amgen case, the patent claims were directed to DNA sequences that encoded amino acid sequences. Because

a very small change in the amino acid sequence of a protein can result in a very large change in the structure-function activity of a protein and because the laws of protein folding are in such a primitive state, predicting protein structure (and hence, activity) while knowing only the sequence of the protein is akin to predicting the weather for a date in the future.

(5) The amount of direction or guidance presented

The amount of guidance or direction needed to enable the invention is inversely related to the degree of predictability in the art. In re Fisher, 839, 166 USPQ 24. Thus, although a single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements, in cases involving unpredictable factors, such as most chemical reactions and physiological activity, more teaching or guidance is required. In re Fischer, 427 F.2d 839, 166 USPQ 24; Ex Parte Hitzeman, 9 USPQ 2d 1823. For example, the Federal Circuit determined that, given the unpredictability of the physiological activity of RNA viruses, a specification requires more than a general description and a single embodiment to provide an enabling disclosure for a method of protecting an organism against RNA viruses. In re Wright, 999 F.2d 1562-63, 27 USPQ2d 1575. In the instant case, given the unpredictability of the physiological or pharmaceutical activity of carbetocin to be effective in treating obsessive-compulsive disorder is insufficient for enablement. In addition, the specification does not provide any enablement of treating the ailment of obsessive-compulsive disorder that could be treated with carbetocin other than treating breast

cancer. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also In re Wright, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993); In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one species, what other species will work. In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result." The article "Broader than the Disclosure in Chemical Cases," 31 J.P.O.S. 5, by Samuel S. Levin covers this subject in detail. A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See In re Riat et al. (CCPA 1964) 327 F2d 685, 140 USPQ 471; In re Barr et al. (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

(6) The presence or absence of working examples

As stated above, the specification alleges that the treatment of OCD can be accomplished with the administration of carbetocin. However, the instant specification only has enablement for the treatment of breast cancer. In fact, the instant specification on page 40 only generically discloses that carbetocin was administered to treat OCD.

This example provides no evidence or guidance on how to interpret these results for the treatment of OCD.

(7) The quantity of experimentation necessary

The quantity of experimentation needed to be performed by one skilled in the art is yet another factor involved in the determining whether "undue experimentation" is required to make and use the instant invention. "'The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.'" In re Wands, 858 F.2d 737, 8 USPQ2d 1404 (citing In re Angstadt, 537 F.2d 489, 502-04, 190 USPQ 214, 218 (CCPA 1976)). For these reasons, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine how carbetocin would be enabled in this specification.

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 31 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

16. Claim 31 recites the limitation "said one or more oxytocin analogue(s)" in line 2. There is insufficient antecedent basis for this limitation in the claim because claim 26 is only directed to carbetocin.

17. Claim 43 recites the limitation "said one or more oxytocin analogue(s)" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim because claims 41 and 39 are only directed to carbetocin.

Claim Rejections - 35 USC § 103

18. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

19. Claims 26, 28-34, 36, 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Copland, III et al. of U.S. Patent No. 6,333,313. Copland, III et al. teach of using the preferred compound and pharmaceutical composition of carbetocin, (see column 5, lines 66-67 and column 6, lines 10-12). In addition, Copland, III et al. teach that carbetocin can be administered in nasal solutions, (see column 10, lines 54-61 and column 13, lines 11-18). Copland, III et al. also disclose that the phrase, "pharmaceutically acceptable carrier" includes any and all solvents, dispersions media, coatings, and the like, (see column 11, lines 7-14). Copland, III et al. also teach of therapeutic amounts for administration, (see from column 12, line 63 to column 13, line 3). Furthermore, Copland, III et al. specifically recited that "[s]upplementary active agents can also be incorporated into the compositions", (see column 11, lines 12-15). In fact, Copland, III et al. specifically recite the combined use

of carbetocin with estrogens/antiestrogens, (see column 14, lines 20-36). It is also noted that the determination of a dosage, mode of administration, addition or removal of pharmaceutically acceptable excipients, salts, diluents and adjuvants that have the optimum therapeutic index is well within the level of one having ordinary skill in the art. In addition, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). For these reasons, the selection of a known material based on its suitability for its intended use, for example psychiatric disorder or breast cancer, supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 US 327, 65 USPQ 297 (1945).

20. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Copland, III et al. of U.S. Patent No. 6,333,313 in view of Windholz, et al., Editor-in-Chief of The Merck Index. Copland, III et al. teach of using the preferred compound and pharmaceutical composition of carbetocin, (see column 5, lines 66-67 and column 6, lines 10-12). In addition, Copland, III et al. teach that carbetocin can be administered in nasal solutions, (see column 10, lines 54-61 and column 13, lines 11-18). Copland, III et al. also disclose that the phrase, "pharmaceutically acceptable carrier" includes any and all solvents, dispersions media, coatings, and the like, (see column 11, lines 7-14).

Copland, III et al. also teach of therapeutic amounts for administration, (see from column 12, line 63 to column 13, line 3). Furthermore, Copland, III et al. specifically recited that "[s]upplementary active agents can also be incorporated into the compositions", (see column 11, lines 12-15). In fact, Copland, III et al. specifically recite the combined use of carbetocin with estrogens/antiestrogens, (see column 14, lines 20-36). It is also noted that the determination of a dosage, mode of administration, addition or removal of pharmaceutically acceptable excipients, salts, diluents and adjuvants that have the optimum therapeutic index is well within the level of one having ordinary skill in the art. Windholz et al. provide an example of an anti-estrogen agent, namely tamoxifen, (see page 1300). In addition, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). For these reasons, the selection of a known material based on its suitability for its intended use, for example psychiatric disorder or breast cancer, supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 US 327, 65 USPQ 297 (1945).

21. The rejection of claims 26, 28-31, 33, 34, 36 and 37 under 35 U.S.C. 103(a) as being unpatentable over Harris et al. of U.S. Patent No. 5,482,931 is maintained and repeated. Harris et al. teach of inter alia, the nasal administration of the preferred

pharmaceutical composition containing carbetocin as well as other analogs of oxytocin, (see column 2, lines 47-55). Harris et al. expands on this nasal composition of carbetocin by providing motivation to use the nasal composition for the management of diseases and abnormal conditions, (cited from column 3, lines 25-29). In addition, Harris et al. teach of adding the pharmaceutically acceptable excipients that contain citrate and/ or phosphate as well as sodium ions, (see column 2, lines 55-67). Harris et al. also teach of the preferred aspect of including at least one mucosal absorption enhancer, (see column 3, lines 13-16). Also, the determination of a dosage, mode of administration, addition or removal of pharmaceutically acceptable excipients, salts, diluents and adjuvants that have the optimum therapeutic index is well within the level of one having ordinary skill in the art. Accordingly, the artisan would have been motivated to determine optimum pharmaceutically acceptable excipients and adjuvants in order to get the maximum effect of the active agent. Moreover, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). For these reasons, the selection of a known material based on its suitability for its intended use, for example psychiatric disorder or breast cancer, supported a prima facie obviousness

determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 US 327, 65 USPQ 297 (1945).

22. The rejection of claims 26, 28-31, 33, 34, 36, 37, and 38 under 35 U.S.C. 103(a) as being unpatentable over Harris et al. in view of Boer et al. and further in view of Leckman et al. is maintained and again repeated. This rejection was found persuasive regarding the reference of Boer et al. Accordingly, this rejection has been modified to a rejection under 35 U.S.C. 103(a) as being unpatentable over Harris et al. in view of Leckman et al. Applicant argues that Leckman et al. fail to teach or suggest the administration of oxytocin to successfully alleviate an obsessive-compulsive disorder in a mammalian subject. In fact, applicant purports that Leckman et al. teach away from the instant invention by allegedly concluding that, "a role for oxytocin in the pathogenesis of obsessive compulsive disorder is meager and has mostly focused on systemically administered oxytocin's equivocal value as a therapeutic agent." This allegation was quoted to show the state of the art from a previously written article, such as Ansseau et al., (see page 734).

23. Leckman et al. do in fact teach that there is, "the emerging role of central OT [oxytocin] in a range of cognitive, grooming, affiliative, and sexual behaviors and how these behaviors are disrupted in some forms of OCD", (see page 735). Leckman et al. also teach that, "there is a considerable body of evidence that OT [oxytocin] is a stress hormone and may serve as an endogenous anxiolytic. ", (see page 736). In fact, Leckman et al. teach that oxytocin can be an anxiolytic agent, because it acted similarly to diazepam; oxytocin acts as an antidepressant; oxytocin elevates pain thresholds and

accordingly induces strong analgesia in man with intractable pain, (see page 737). For these reasons, Leckman et al. provides the skilled artisan with the motivation to use oxytocin to treat "anxiety disorders . . . [such as] OCD", (see page 737). In addition, the skilled artisan would have been motivated to employ oxytocin and its related derivatives to treat psychosis, such as OCD. Furthermore, the skilled artisan is provided with the teaching that patients with oxytocin-related OCD may be more responsive to serotonin reuptake inhibitors, (see Leckman et al., page 739). In fact, Leckman et al. specifically teach of a study where virtually all patients with OCD, "responded well to 5-HT reuptake inhibitors", (as cited from page 739). For these reasons, it would have been obvious to the skilled artisan to combine a serotonin reuptake inhibitor along with the administration of oxytocin and its analogues, which include carbetocin. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . .[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Furthermore, these rejected claims are composition claims with an intended use.

24. Claims 26, 28-31, 33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Copland, III et al. of U.S. Patent No. 6,333,313. Copland, III et al. teach of the pharmaceutical administration of oxytocin analog of carbetocin, (see column 3, lines 29, 30, 35-41 and from column 5, line 66 to column 6, line 11). In addition, Copland, III et al. teach of various modes of administration, in particular nasal

administration, (see column 3, lines 45-48). Copland, III et al. also teach of various pharmaceutically acceptable carriers, solvents, dispersion media, agents, and like, which may be combined, (see column 11, lines 7-15 and column 13, lines 11-25). In addition, Copland, III et al. disclose of active therapeutic amounts ranging from 0.0001 milligrams to 10 milligrams, (see column 12, line 63 to column 13, line 3). Copland, III et al. furthermore teach of the addition of other preservatives and stabilizers as well as explicit teachings of combination therapies that include inter alia, estrogens/antiestrogens, (see column 14, lines 20). It is well established in the caner art that tamoxifen is considered antiestrogen agent This reference clearly provides the artisan with the motivation to vary and select various pharmaceutically acceptable agents, excipients, solvents and diluents. Moreover, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). For these reasons, the selection of a known material based on its suitability for its intended use, for example psychiatric disorder or breast cancer, supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 US 327, 65 USPQ 297 (1945).

Allowable Subject Matter

25. Claims 1, 3-12 are allowed.

Double Patenting

26. Claim 23 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 22. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

27. Claims 39, 41, 42, 44, and 46-50 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 1, 3, 4, 6, and 8-12. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

DWAYNE C. JONES
PRIMARY EXAMINER
Tech. Ctr. 1614
January 26, 2004